



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355795	ElderForte
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	26/02/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . ElderForte

Product Type	Single Medicine Product	Effective Date	26/02/2021
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Permitted Indications

Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
Traditionally used in Western herbal medicine to antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
Traditionally used in Western herbal medicine to maintain/support healthy lymphatic system
Traditionally used in Western herbal medicine to maintain/support immune system health
Traditionally used in Western herbal medicine to maintain/support healthy immune system function
Traditionally used in Western herbal medicine to decongestant/relieve nasal congestion
Traditionally used in Western herbal medicine to decrease/reduce/relieve common cold duration
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections
Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of common cold symptoms
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold
Traditionally used in Western herbal medicine to antitussive/cough suppressant
Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
Product presentation must not imply or refer to serious immunological diseases.
Product presentation must not imply or refer to serious cardiovascular conditions.
Respiratory tract infections must be qualified by 'mild'.
Label statement: Not to be used in children under 5 years.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information**Pack Size/Poison information****Pack Size****Poison Schedule****Components****1 . Formulation 1**

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification**Active Ingredients**

Calendula officinalis flower Extract dry concentrate	90 mg
Equivalent: Calendula officinalis (Dry)	1.35 g
Echinacea purpurea root Extract dry concentrate	30 mg
Equivalent: Echinacea purpurea (Dry)	1.5 g
Eupatorium perfoliatum flower and leaf Extract dry concentrate	150 mg
Equivalent: Eupatorium perfoliatum (Dry)	1.5 g
Inula helenium root Extract dry concentrate	300 mg
Equivalent: Inula helenium (Dry)	3 g
Sambucus nigra flower Extract dry concentrate	133.33 mg
Equivalent: Sambucus nigra (Dry)	2 g
Sambucus nigra fruit Juice dry	125 mg
Equivalent: Sambucus nigra (Juice fresh)	3.75 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
crospovidone
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone

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